REMARKS/ARGUMENTS

Claims 1-22 were pending in this application. Claims 7-18 were withdrawn. By this Amendment, claims 1-3 and 19 have been amended. No new matter has been added. Accordingly, claims 1-6 and 19-22 are pending.

The Examiner stated that the title is not descriptive.

In response, applicants have amended the title which now reads, "Use of Compounds in Therapy of Cachexia and Wasting Syndromes."

The Examiner objected to claim 19 as being in improper form.

In response, applicants have amended claim 19 which now depends on one claim only.

Claim Rejections under 35 U.S.C. 112, second paragraph

The Examiner rejected claims 1-6 and 19-22 as being indefinite.

In response, applicants have taken out the term, "LPS" from claims 1-3 and amended claim 2 now reads in part, "A method according to claim 1, further comprising....."

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw these rejections.

Claim Rejections under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 1-6 and 19-22 as not being enabled.

In response, applicants have amended independent claim 1 and claim 2 which are now directed to "a method of reducing endotoxin induced cytokine production in a patient suffering from cachexia or body wasting in a patient with liver cirrhosis." Claims 3-6 and 19-22 either directly or indirectly depends on claim 1. Applicants have deleted the references to other diseases except for liver cirrhosis which is supported in the specification by Examples 1-4.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claim Rejections under 35 U.S.C. 102(b)

The Examiner rejected claims 1-6 and 19-20 as being anticipated by U.S. Patent 5,639,744, as evidenced by U.S. Patent 4,377595 and/or U.S. Patent 4,898,879.

In response, applicants assert that these references do not teach or suggest every element of the claimed invention. None of these references describe a method of reducing endotoxin induced cytokine production in a human patient suffering from cachexia or body wasting comprising administering to the human patient an effective amount of a compound that is able to reduce the production, absorption and/or the effect of an endotoxin. In addition, none of these references in describing a method of treating liver diseases comprising administering to a patient an effective amount of UDCA uses human data to support their disclosures as in the claimed invention. The '744 patent only uses rat data. The '595 patent only uses rat data. The '879 patent does not even mention comprising administering to a patient an effective amount of UDCA. The claimed invention as shown in Examples 1-4 uses in vivo human data. There is not necessarily a correlation between rat and human efficacy.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim Rejections under 35 U.S.C. 102(e)

The Examiner rejected claims 1-6 and 19-21 as being anticipated by U.S. Patent 6,251,884 as evidenced by U.S. Patent 4,377,595 and/or U.S. Patent 4,898,879.

In response, applicants point to the arguments described above and in addition, mention that the '884 patent only uses rat data in describing a method of treating liver diseases comprising administering to a patient an effective amount of UDCA. As mentioned above, there is not necessarily a correlation between rat and human data in terms of efficacy.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim Rejections under 35 U.S.C. 102(e)

The Examiner rejected claims 1-6 and 19 as being anticipated by U.S. Patent 5,869,265 as evidenced by U.S. Patent 4,377,595 and/or U.S. Patent 4,898,879.

In response, applicants point to the arguments described above and in addition, mention that the '265 patent does not use any human data in describing a method of reducing endotoxin induced cytokine production in a human patient suffering from cachexia or body wasting comprising administering to the human patient an effective

amount of a compound that is able to reduce the production, absorption and/or the effect of an endotoxin as in the claimed invention.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Claim Rejections under 35 U.S.C. 103(a)

The Examiner rejected claims 1-6 and 19-22 as being obvious over U.S. Patent 6,251,884 or U.S. Patent 5,869,265 or U.S. Patent 5,639,744 each in view of U.S. Patent 4,377,595 and/or U.S. Patent 4,898,879.

In response, applicants assert that these references individually or combined do not teach or suggest every element of the claimed invention. None of these references describe a method of reducing endotoxin induced cytokine production in a human patient suffering from cachexia or body wasting comprising administering to the human patient an effective amount of a compound that is able to reduce the production, absorption and/or the effect of an endotoxin. In addition, none of these references individually or taken as a whole in describing a method of treating liver diseases comprising administering to a patient an effective amount of UDCA uses human data to support their disclosures as in the claimed invention. The '744 patent only uses rat data. The '595 patent only uses

rat data. The '879 patent does not even mention comprising administering to a patient an effective amount of UDCA. The '884 patent only uses rat data in describing a method of treating liver diseases comprising administering to a patient an effective amount of UDCA. The '265 patent does not use any human data in describing a method of reducing endotoxin induced cytokine production in a human patient suffering from cachexia or body wasting comprising administering to the human patient an effective amount of a compound that is able to reduce the production, absorption and/or the effect of an endotoxin as in the claimed invention. The claimed invention as shown in Examples 1-4 uses in vivo human data. There is not necessarily a correlation between rat and human efficacy.

Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

Based on the foregoing remarks it is believed that the claim is in condition for allowance.

Respectfully Submitted,

Norris, McLaughlin & Marcus
875 Third Avenue
18th Floor
New York, NY 10022
Telephone (212) 808-0700
Facsimile (212) 808-0844

Paul Lim
Reg. No. 55,383

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